

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K033864

B. Analyte:

Trichomonas vaginalis antigens

C. Type of Test:

Chromatographic, lateral flow immunoassay, qualitative

D. Applicant:

Genzyme General Diagnostic.

E. Proprietary and Established Names:

OSOM® Trichomonas Rapid Test

F. Regulatory Information:

1. Regulation section:
21 CFR Part 866.2660 Microorganism Differentiation and Identification
Limitation: 21 CFR 866.9 (6)
2. Classification:
Class I
3. Product Code:
JWZ – Trichomonas screening
4. Panel:
83 (Microbiology)

G. Intended Use:

5. Intended use(s):
The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of Trichomonas vaginalis (Trichomonas) antigens from vaginal swabs or from the saline solution prepared when making wet mounts from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen.
6. Indication(s) for use:
This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen. This device is intended for use in physicians' offices as well as clinical laboratories.
7. Special condition for use statement(s):
Prescription Use.
8. Special instrument Requirements:
Not applicable

H. Device Description:

The OSOM® Trichomonas Rapid Test kit is a color, immunochromatographic, lateral-flow "dipstick" assay. The test procedure requires the dissolving of Trichomonas proteins from a vaginal swab by mixing the swab in sample buffer. The device test stick is placed in the sample mixture and the mixture migrates along the membrane surface by capillary action. If Trichomonas is present in the sample, it will form a complex with the

primary anti-Trichomonas antibody conjugated to colored (blue) particles. The complex is then bound by a second anti-Trichomonas capture antibody at the end of the membrane. The appearance of a visible blue test line together with the red control line indicates a positive result.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Xenotope XenoStrip® -Tv Test
2. Predicate K number(s):
K 020226
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The OSOM® Trichomonas Rapid Test is intended for the qualitative detection of <i>Trichomonas vaginalis</i> (“Trichomonas”) antigens from vaginal swabs or from the saline solution prepared when making wet mounts from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected exposure to the Trichomonas pathogen.	The Xenotope Diagnostics’ Inc. XenoStrip™ -Tv Trichomonas Test is intended for the qualitative detection of Trichomonas vaginalis (“Trichomonas”) antigens from vaginal swabs. This test is intended for use in patients with symptoms of vaginosis/vaginitis or suspected or suspected exposure to the pathogen.
Technology	Lateral flow	Lateral flow
Antibodies (labeled and capture)	Mouse monoclonal antibodies	Mouse monoclonal antibodies
Specimen type	vaginal swabs saline solution prepared for wet mount microscopy	vaginal swabs
Indication for Use	Professional Use	Professional Use
Internal control	Yes-red line	Yes-red line
Differences		
Item	Device	Predicate
conjugate	latex	Colloidal gold
Analytical sensitivity	2500 organisms/ml	1-10 organisms/swab
Clinical sensitivity	Vaginal swab 83% Saline from wet mount 75%	100%
Clinical specificity	99 %	98.1%

J. Standard/Guidance Document Referenced (if applicable):

Not applicable

K. Test Principle:

The OSOM® Trichomonas Rapid Test uses color immunochromatographic, capillary flow, “dipstick” technology. The test procedure requires the dissolution of Trichomonas proteins from a vaginal swab by mixing it in a sample buffer.

The dipstick is then placed in the sample mixture and the mixture migrates along the membrane surface. If Trichomonas is present in the sample, it will form a complex with the primary anti-Trichomonas antibody conjugated to colored (blue) particles. The complex is subsequently bound by the second anti-Trichomonas capture antibody. The appearance of a visible blue test line together with the red control line indicates a positive result.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility testing was conducted by two operators, on three lots, for 5 separate days with blinded samples of varying activity. A total of 540 samples were tested with no discordant results.

b. Linearity/assay reportable range:

Not applicable

c. Traceability (controls, calibrators, or method):

Not applicable

d. Detection limit:

The OSOM® Trichomonas Rapid Test consistently detected antigen derived from 2500 organisms per ml.

e. Analytical specificity:

Cross-reactivity:

Cross-reactivity studies were performed using the OSOM® Trichomonas Rapid Test. The following organisms were tested at least 1×10^8 organisms/ml. *T. foetus*, *C. trachomatis*, and *C. albicans* samples tested at approximately 0.5×10^5 organisms per ml.

Bacteriodes merdae	Lactobacillus acidophilus	Salmonella typhimurium
Candida albicans	Mobuluncus curtesii	Shigella flexneri
Chlamydia trachomatis	Tritrichomonas foetus	Streptococcus agalactiae
Escherichia coli	Monella choleraesuis	Staphylococcus aureus
Gardnerella vaginalis	Neisseria gonorrhoeae	Streptococci Group B

Interfering Substances:

Other interfering substance testing was also performed.

Condoms, with spermicide	TYM Culture Medium
HeLa cells	HVEC cells
Douche (vinegar)	Human blood
Vaginal yeast treatment (Monistat® brand)	

The testing demonstrated that the potentially interfering substances do not cross react with the OSOM® Trichomonas Rapid Test with the exception of high concentrations of Staphylococcus aureus at concentrations $> 1 \times 10^8$. In addition, douche medicated with iodine diluted 1:2 and K-Y Jelly diluted 1:4 also showed some degree of cross reactivity.

f. Assay cut-off:

The assay detection limit is 2500 organisms per ml.

Clinically relevant detection limits were determined using laboratory cultured samples of *Trichomonas vaginalis*. *T. vaginalis* was adjusted to stock concentrations of 1.33×10^4 and 1.0×10^4 organisms per ml. Two fold serial dilutions were performed on each stock. The lowest concentration tested was 8.33×10^2 organisms per ml.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical sensitivity:

Sensitivity and Specificity Compared to Wet mount, and Culture:

A total of 449 patients, 448 of the wet mount saline samples and 439 swabs were received for testing with the device. 445 samples for culture utilizing the InPouch™ testing were read. Patients were selected based on presentation of symptoms of vaginosis/vaginitis or suspected exposure to Trichomonas infection. Three swabs were collected from each patient. One swab was randomly selected from the three and evaluated by standard wet mount microscopy. The wet mount was conducted at the investigational site. Another swab, selected randomly, was used for direct inoculation of a BioMed In-Pouch™ culture performed at the clinical site. The remaining swab was frozen for shipment to Genzyme for testing on the OSOM device. The swab and solution remaining from the wet mount microscopy was frozen and sent to Genzyme for testing with the OSOM device.

The results are summarized as follows:

Sensitivity, and Specificity

Table 1
COMPARISON OF OSOM® TRICHOMONAS RAPID TEST TO
WET MOUNT MICROSCOPY

		Wet Mount Microscopy		Total
		+	-	
OSOM® Trichomonas Rapid Test (vaginal swab)	+	69	20*	89
	-	3	345	348
Total		72	365	437

*Of the 20 samples negative by wet mount, 16 were positive by culture and 4 were negative.

Sensitivity: 69/ 72 = 96% (91-100%)

Specificity: 345/ 365 = 95% (92-97%)

Agreement: 414/ 437 = 95% (93-97%)

*(Confidence intervals in parenthesis)

Table 2
COMPARISON OF OSOM® TRICHOMONAS RAPID TEST
TO COMPOSITE REFERENCE STANDARD

		Composite Reference Standard		Total
		+	-	
OSOM® Trichomonas Rapid Test (vaginal swab)	+	85	4	89
	-	17	331	348
Total		102	335	437

Sensitivity: 85/ 102 = 83% (76-91%)

Specificity: 331/ 335 = 99% (98-100%)

Agreement: 416/ 437 = 95% (93-97%)

Table 3
COMPARISON OF OSOM® TRICHOMONAS RAPID TEST
SALINE FROM WET MOUNT SAMPLE
TO COMPOSITE REFERENCE STANDARD

		Composite Reference Standard		Total
		+	-	
OSOM® Trichomonas Rapid Test (saline from wet mount)	+	79	5	84
	-	26	337	363
Total		105	342	447

Sensitivity: 79/ 105 = 75% (67-84%)
 Specificity: 337/ 342 = 99% (97-100%)
 Agreement: 416/ 447 = 93% (91-95%)

Table 4
SENSITIVITY OF EACH METHOD
VERSUS COMPOSITE REFERENCE STANDARD

Method	Sensitivity
OSOM® Trichomonas Rapid Test (vaginal swab)	83%
OSOM® Trichomonas Rapid Test (saline from wet mount)	75%
Wet Mount Microscopy	71%
Culture (InPouch™ TV)	99%

b. Clinical specificity:

Refer to (a) above

c. Other clinical supportive data (when a and b are not applicable):

Not applicable

4. Clinical cut-off:

See assay cut off above

5. Expected values/Reference range:

Studies have shown that the incidence of Trichomonas infections by culture in women presenting to STD clinics is between 8-37%. In a clinical trial involving the OSOM Trichomonas Test at eight sites, including STD clinics, hospital emergency departments, and public health clinics, the incidence of Trichomonas infections detected by culture or wet mount ranged from 13% to 29%. Up to 50% of women infected with Trichomonas may not be aware of symptomology. The highest incidence of this disease is found in women with at-risk factors that predispose them to acquiring sexually transmitted diseases. Trichomoniasis also has a high likelihood of co-infection with other STDs, including those that also result in symptoms of vaginitis.

M. Conclusion:

In clinical settings, the OSOM® Trichomonas Rapid Test is substantially equivalent in performance to the predicate device and to culture examination for the identification of *Trichomonas vaginalis* in vaginal swabs and saline solution prepared when making wet mounts from vaginal swab specimens.